DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ASSISTANT SECRETARY AND COMMISSIONER
98 SEP -6 PM 2:01
U.S. PATENT AND TRADEMARK OFFICE

Re: Normiflo
Docket No.: 97E-0367

#28

SEP 29 1998

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,757,057, filed by Pharmacia & Upjohn Aktiebolag, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Normiflo, the human drug product claimed by the patent.

The total length of the regulatory review period for Normiflo is 3503 days. Of this time, 1883 days occurred during the testing phase and 1620 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: October 22, 1987.

   The applicant claims September 21, 1987, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 22, 1987, which was thirty days after FDA receipt of the IND./

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 16, 1992.

   The applicant claims February 28, 1992, as the date the New Drug Application (NDA) for Normiflo (NDA 20-227) was initially submitted. However, FDA records indicate that NDA 20-227, submitted on February 28, 1992, was incomplete. The FDA refused this application and notified the applicant of this fact by letter dated April 20, 1992. The completed NDA was then submitted on December 16, 1992, which is considered to be the NDA initially submitted date.

3. The date the application was approved: May 23, 1997.

FDA has verified the applicant's claim that NDA 20-227 was approved on May 23, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

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